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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,042	06/27/2007	**Michael Karin**	UCSD-10879	5600

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
12/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,042	KARIN ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,20-25 and 64-66* is/are pending in the application.

4a) Of the above claim(s) *1-17,21,25 and 64-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group II filed 10/13/09 is acknowledged.

2. Claims 1-17, 21, 25, and 64-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Claims 20 and 22-24 are under examination.

3. The Abstract and the Title are objected to because they do not adequately describe the claimed invention. Applicant is advised that an Abstract and Title commensurate in scope with the invention of the instant claims are required. In particular the Abstract and Title must disclose that which is novel to the claimed invention. i.e., a method involving altering Itch activity. See MPEP 608.01(b).

4. The Declaration is objected to because it is illegible. A new declaration is required.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 20 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, Claims 20, 22 and 24 is vague and indefinite as the resolutions of the claims do not match the preambles. The claims recite a method of increasing Th2 cytokine levels yet the results of the claims are detecting reduced Itch activity (Claim 20), and identifying a test agent (Claims 22 and 24). It appears that Applicant has mixed and matched steps from different types of methods, i.e., a method of treating and a method of identifying test agents suitable for treating.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 20 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of:

A) An inhibitor of ITCH,
B) ITCH,
C) A test agent.

Regarding the "ITCH" of the claims, the specification fails to adequately describe the protein. The specification merely cites Fang et al. (2002) and Qiu et al. (2000). These references teach only that ITCH is an E3 ubiquitin ligase and that the gene encoding said protein is disrupted in "itchy" mice (pages 38 and 39). Note that the references disclose essentially nothing about the protein itself, only the result of it's absence. Accordingly, no species of ITCH are actually described. No common structure (of all ITCHs) is defined and neither is a common function. While it might be assumed that the common function might be ligase activity, the specification makes clear that the definition is not to be so limited. The specification discloses that, "any specifically named protein (such as … itch…) refers to any and all equivalent fragments, fusion proteins, and variants of the specifically named protein, having at least one of the biological activities (such as those

disclosed herein and/or known in the art) of the specifically named protein, wherein the biological activity is detectable by any method" (page 31). "Fragments" and "variants" are defined even more broadly (pages 31 and 32). Clearly, neither specific structure and function, nor an adequate number of representative species of ITCH, are disclosed in the instant specification. One of skill in the art would therefore conclude that the specification fails to adequately describe ITCH.

Regarding the "inhibitor of ITCH" of the claims, the specification fails to even disclose the term. Clearly then one of skill in the art would conclude that the specification fails to adequately describe said inhibitor.

Regarding the "test agent" of the claims, no species of said agents are disclosed. The specification describes said agent at page 29, "the term "test agent" refers to any chemical entity, pharmaceutical, drug, and the like that can be used to treat or prevent a disease, illness, sickness, or disorder of bodily function. Test agents comprise both known and potential therapeutic agents. A test agent can be determined to be therapeutic by screening using the screening methods of the present invention. A "known therapeutic agent" refers to a therapeutic agent that has been shown *(e.g.,* through animal trials or prior experience with administration to humans) to be effective in such treatment or prevention. In other words, a known therapeutic agent is not limited to an agent efficacious in the treatment of disease *(e.g.,* cancer). Agents are exemplified by, but not limited to, antibodies, nucleic acid sequences such as ribozyme sequences, and other agents as further described herein". Thus, it is clear that said agents encompass structurally unrelated molecules including antibodies, nucleic acid sequences and ribozymes, defined only by an unknown function. Again, one of skill in the art would conclude that the specification fails to adequately describe said agents. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

> art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2004/0259790 in view of Fang et al. (2002).

The '790 application teaches the concept the T helper cell (Th)immune response being either a Th1 type response or a Th2 type response. Skewing the response towards either Th1 or Th2 lowers the other response, i.e., if the Th2 response is raised, the Th1 response is lowered (see particularly the Background, [0019], and [0025]). The reference teaches that the responses can be characterized by identifying the cytokine profiles generated, e.g., IFN-γ in a Th1 response and IL-4, IL-5, and IL-13 in a Th2 response (see particularly [0056]). The reference further teaches that actual manipulation of the Th1/Th2 balance by administering appropriate agonists and antagonists (see particularly [0021] and [0058]). The reference specifically teaches the increasing of a Th2 response (which would include an increase in Th2 cytokine levels) (see particularly [0077]).

The reference teaching differs from the claimed invention only in that it does not teach the providing of a test agent that reduces ITCH activity to produce the claimed increase in Th2 cytokines.

Fang et al. teach that ITCH deficient mice show increased Th2 type immune response and increased production of Th2 cytokines including IL-4 and IL-5 (see particularly the Abstract and Figure 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of skewing the immune response towards Th2, which would necessarily include the production of increased Th2 cytokine levels including IL-4, IL-5, and IL-13, as taught by the '790 application, by providing an ITCH inhibitor given the teachings of Fang et al. that the lack of ITCH results in an increase of the Th2 immune response and an increased level of Th2 cytokines. The provision of an ITCH inhibitor comprises no more than the substitution of an equivalent antagonist to those of the '790 application. It is well-established that the substitution of known equivalents is obvious. Note that the '790 application also teaches the providing of Th1 antagonists (which would

decrease the levels of Th1 cytokines) and the identifying of increased and decreased TH1 and Th2 cytokine levels.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0841.

13. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

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